K081482

Toshiba America Medical Systems, Inc.
Pre-Market Notification 510(k) for CSBP-001A Body Organ Perfusion System

510(k) Summary

JUN 11 2008

Date:	May 12, 2008
Submitter's Name:	Toshiba America Medical Systems, Inc.
Submitter's Address:	P.O. Box 2068, 2441 Michelle Drive, Tustin, CA 92781-2068
Submitter's Contact: (714)730-5000	Paul Biggins, Regulatory Affairs Specialist,
Establishment Registration Number:	2020563
Device Proprietary Name:	CSBP-001A; Body Organ Perfusion System
Common Name:	Scanner, Computed Tomography, X-Ray [Fed. Reg. No. 892.1750, Pro. Code: 90JAK]
Regulatory Class:	II (per 21 CFR 892.1750)
Performance Standard: Standard	21 CFR Subchapter J, Federal Diagnostic X-ray Equipment
Predicate Device(s):	GE CT Perfusion 4 (k052839) Siemens Symgo Perfusion (k073373) Philips Brilliance CT (k060397)
Reason For Submission	New Device

Description of this Device:
The CSBP-001A is post-processing software that does not affect the operation of the parent CT System. This software provides analysis tools that are used on a series of dynamic images (images collected over time) to provide numerical values related to tissue perfusion of organs, tumors lesions, etc. Additionally, this software will allow for the display of perfusion maps.

Summary of Intended Uses:
The CSBP-001A is a non-invasive post processing package that can be used to evaluate perfusion of the organs, tissue, tumors and lesions; this type of application is useful in assisting in the diagnosis of disease and providing information for following treatment.

Toshiba America Medical Systems, Inc.
Pre-Market Notification 510(k) for CSBP-001A Body Organ Perfusion System

Safety and Effectiveness Concerns:
This device is designed and manufactured under the Quality System Regulations as outlined in 21 CFR § 820. Bench test data is provided in the submission to provide evidence of the safety and effectiveness of this device.

Substantial Equivalence:
This software package provides information to the user that is similar to that which is provided by the predicate devices. The information is obtained in a manner that is similar to the predicate devices, or in a manner that is a combination of the predicate devices. Additionally, the indications for use and intended uses are identical to the predicate devices. There are no new indications for use that are not already available in devices already marketed in the U.S.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 11 2008

Toshiba America Medical Systems, Inc.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1395 25th Street NW
BUFFALO MN 55313

Re: K081482
Trade/Device Name: CSBP-001A, Body Organ Perfusion System
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: May 27, 2008
Received: May 28, 2008

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Toshiba America Medical Systems, Inc.
Pre-Market Notification 510(k) for CSBP-001A Body Organ Perfusion System

Indications for Use

510(k) Number (if known):

Device Name: CSBP-001A, Body Organ Perfusion System

Indications for Use:

This software package has been designed to evaluate the perfusion of organs and tumors.

The software allows for the calculation of blood flow, blood volume and permeability from sets pf images reconstructed from dynamic CT data acquired after the injection of a contrast bolus.

The package also allows for the independent calculation of arterial and portal venous component of hepatic perfusion. It supports the evaluation of regions of interest and the visual inspection of time density curves.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K081482